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Clariant Corporation  
4000 Monroe Road

August 4, 2011

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TSCA Section 8(e) Report of Local Lymph Node Assays (LLNA) on  
dibromobenzanthrone (81-98-1), an impurity in 3-benzobenzanthranone (81-96-9)

Dear TSCA Section 8(e) Coordinator:

On July 7<sup>th</sup> 2011, we received 3 LLNA study summaries which examined the sensitization properties of dibromobenzanthrone (81-98-1), an impurity in 3-benzobenzanthrone (81-96-9). 3-Benzobenzanthranone is used as a starting raw material in the production of C.I. Solvent Orange 63 (16294-75-0).

Three samples of C.I. Solvent Orange 63 containing 0.5, 1.9 or 8.3% (w/w) dibromobenzanthrone were tested in the Local Lymph Node Assay (LLNA) according to OECD Guideline 429. These three samples were applied at C.I. Solvent Orange 63 concentrations of 25, 25, and 10%, respectively. The concentrations of the test item were determined to be the highest technically achievable concentration without systemic toxicity or excessive local irritation.

In the studies, four female mice were treated with a single concentration of the test item and vehicle alone by topical application at the dorsum of each ear lobe (left and right) on three consecutive days. Five days after the first topical application, the mice were intravenously injected into a tail vein with radio-labeled thymidine (<sup>3</sup>H-methyl thymidine). Five hours after intravenous injection, the mice were sacrificed and the draining auricular lymph nodes excised and pooled per group. Single cell suspensions of lymph node cells were prepared from pooled lymph nodes which were subsequently washed and incubated with trichloroacetic acid overnight. The proliferative capacity of pooled lymph node cells was determined by the incorporation of <sup>3</sup>H-methyl thymidine measured in a  $\beta$ -scintillation counter.

The proliferative response of lymph node cells was expressed as the number of radioactive disintegrations per minute (DPM) per lymph node and as the ratio of <sup>3</sup>HTdR incorporated into lymph node cells of test lymph nodes relative to that recorded for



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control lymph nodes (stimulation index). In addition to the sensitizing reactions, the following observations and data were recorded: mortality/viability once daily, body weights prior to the first application and prior to necropsy, clinical signs (local/systemic) daily from start to the termination of in-life phase.

No deaths occurred in the three studies. Likewise, no systemic toxicity or local toxicity of the ears was observed. Body weights were within historical control range for the duration of the three studies. Sensitization results are described in the table below.

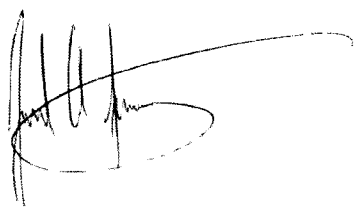
**Sensitization results for the three studies**

Study	Solvent Orange 63 Concentration (%)	Dibromobenzanthrone Concentration (%)	DPM	DPM/Lymph Node (n=8)	Stimulation Index (SI)
1	0	0	6044.7	755.6	
1	25	0.5	13,344.0	1668.0	2.2
2	0	0	4477.9	559.7	
2	25	1.9	20199.6	2524.9	4.51
3	0	0	4477.9	559.7	
3	10	8.3	18413.2	2301.6	4.11

A substance was considered sensitizer if it produced a Stimulation Index (SI) of 3 or greater. Based on this criterion, the substances tested in studies 2 and 3 would be considered sensitizing with SI's of 4.51 and 4.11, respectively. The substance in study 1 is classified as non-sensitizing. EC3's were not calculated for the individual studies because only a single concentration was tested.<sup>1</sup>

I hope that you find this information useful and informative. If you have any questions, please feel free to contact me.

Sincerely,



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<sup>1</sup> The EC3 is the concentration at which an SI of 3 is calculated to occur.

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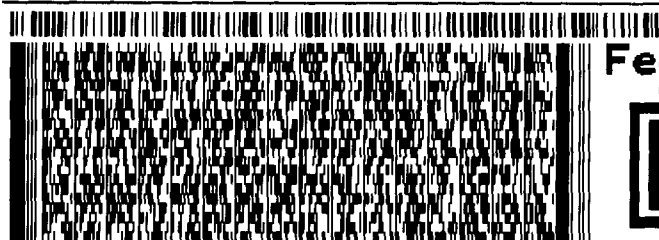
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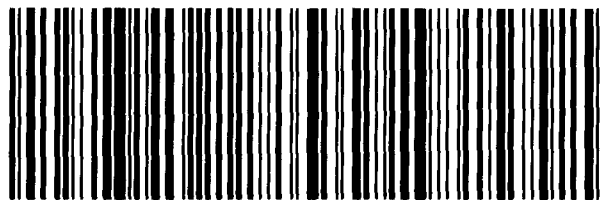


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